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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/712,486	11/13/2003	David A. Schechter	2876	8330
50855	7590	08/14/2006	EXAMINER TOY, ALEX B	
UNITED STATES SURGICAL, A DIVISION OF TYCO HEALTHCARE GROUP LP 195 MCDERMOTT ROAD NORTH HAVEN, CT 06473			ART UNIT	PAPER NUMBER 3739

DATE MAILED: 08/14/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/712,486	SCHECHTER ET AL.	
	Examiner	Art Unit	
	Alex B. Toy	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 09 June 2006.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) 6 and 9-20 is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-5,7,8 and 21-23 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 13 February 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>3/17/06; 6/19/06</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Response to Amendment

This Office Action is in response to applicant's amendment filed on June 9, 2006.

The objections to the drawings and claim 8 are withdrawn in view of applicant's amendments to the claims. All previous prior art rejections are maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 22 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicant has not provided any support to enable the use of the more specific range of about 0.005 inches to less than 0.04 inches.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.



Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Hooven (U.S. Pat. No. 6,086,586).

Regarding claim 1, Hooven discloses a tissue or vessel sealing instrument, comprising:

a housing 14 having a shaft 28 attached thereto (Fig. 2); and

an end effector 22, 24 assembly attached to a distal end of the shaft, the end effector assembly including first 22 and second 24 jaw members attached thereto made from a substantially rigid material (col. 4, ln. 46-49), the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween (Figs. 2, 4c, and 6);

each of the jaw members including an elastomeric material 50, 52 disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode 42, 44, 46, 48 disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated, electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces (col. 4, ln. 30-34 and Figs. 5-6 and 9), the elastomeric material being adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi.

Regarding claim 2, Hooven discloses the tissue or vessel sealing instrument of claim 1, wherein the elastomeric material 50, 52 is ABS (col. 4, ln. 46-49).

Regarding claim 3, Hooven discloses the tissue or vessel sealing instrument of claim 1, wherein the offset distance X is in the range of about 0.005 inches (0.127 mm) to about 0.200 inches (5.08 mm) (col. 4, ln. 63-65 and Fig. 9).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 4-5 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven ('586) in view of Klicek (U.S. Pat. No. 5,496,312).

Hooven discloses the tissue or vessel sealing instrument of claim 1, wherein at least one of the jaw members 22, 24 includes a plurality of electrodes 42, 44, 46, 48 across the width thereof (Figs. 5-6). The claims differ from Hooven in calling for a sensor that measures at least one of tissue impedance, tissue temperature, and tissue

thickness to regulate the applied electrosurgical energy by selecting one of the plurality of electrodes for electrically opposing the electrode disposed on the other of the jaw members.

Klicek, however teaches a bipolar electrosurgical instrument with multiple electrodes 18, comprising at least one impedance or temperature sensor 19, 23, which provides information to a feedback circuit for regulating the applied electrosurgical energy by selecting one of the plurality of electrodes for electrically opposing the electrode disposed on the other of the jaw members (col. 5, ln. 50-54, col. 6, ln. 4-39, and Figs. 3 and 6). This allows the instrument of Klicek to recognize variations in tissue impedance and temperature in closely located tissues and accommodate those variations with automatic control that responds independently to the tissue at each active electrode contact.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the instrument of Hooven in accordance with claims 4-5 and 7 in view of the teachings of Klicek in order to allow finer control of the amount of applied electrosurgical energy. Using the sensor/control system of Klicek would allow the user of the Hooven instrument to activate only one of the two opposing electrode pairs to better control the intensity and rate of treatment based on the tissue type.

Claim 8 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Hooven ('586).

Regarding claim 8, Hooven discloses the tissue or vessel sealing instrument of claim 1, wherein the elastomeric material has a comparative tracking index value of about 300 to about 600 volts. Since the elastomeric material of Hooven (see rejection of claim 2) is identical to applicant's disclosed elastomeric material, they are deemed to inherently, or at least obviously, possess the same comparative tracking index value.

Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hooven ('586).

Regarding claim 21, Hooven discloses a tissue or vessel sealing instrument, comprising:

a housing 14 having a shaft 28 attached thereto (Fig. 2); and

an end effector 22, 24 assembly attached to a distal end of the shaft, the end effector assembly including first 22 and second 24 jaw members attached thereto made from a substantially rigid material (col. 4, ln. 46-49), the jaw members being movable relative to one another from a first position for approximating tissue to at least one additional position for grasping tissue therebetween (Figs. 2, 4c, and 6);

each of the jaw members including an elastomeric material 50, 52 (col. 4, ln. 46-49) disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode 42, 44, 46, 48 disposed therein, the electrodes being offset a distance X relative to one another such that when the jaw members are closed about the tissue and when the electrodes are activated,

electrosurgical energy flows through the tissue in a generally coplanar manner relative to the tissue contacting surfaces (col. 4, ln. 30-34 and Figs. 5-6 and 9).

The claim differs from Hooven in calling for the elastomeric material to be at least one of a specific type of material that is adapted to compress or deflect about 0.001 inches to about 0.015 inches when the force used to close the jaw members is between about 40 psi to about 230 psi. Although applicant has removed polycarbonate and ABS from the claimed list, the specification still discloses that the other materials on the list are obvious equivalents of polycarbonate and ABS since applicant has not disclosed any criticality or unexecpted result associated with any individual material. Furthermore, it would require only routine skill in the art to select one of the claimed elastomeric equivalents to polycarbonate or ABS since many of the claimed materials are obvious to one of ordinary skill in the art.

Finally, since applicant discloses in dependent claim 2 a list of elastomeric materials, the list must inherently be adapted to have the specific compression range at the specific jaw closure force range as specified in claim 1. Therefore, the claimed material chosen for use in Hooven as a matter of obviousness must inherently be adapted to have the specific compression range at the specific jaw closure force range as claimed.

Regarding claim 22, see the preceding rejection of claim 1. The claim differs from Hooven in calling for the offset distance X to be in the range of about 0.005 inches to less than 0.04 inches. Applicant, however, has not provided any criticality or unexpected result derived from using this specific range that defines over the 1 mm to 6 mm range

disclosed by Hooven (col. 5, ln. 2-3). Furthermore, since the ranges are so close, it would have been obvious and required only routine skill in the art to use a distance slightly less than 1 mm (0.04 inches) in the device of Hooven. Finally, as stated in the preceding 112, first paragraph rejection, applicant has not provided any support to enable the use of this more specific range.

Regarding claim 23, see the preceding rejection of claim 1. The claim differs from Hooven in calling for the distance X to be variable depending on the thickness of the tissue between the jaw members. However, it is obvious and intuitive to one of ordinary skill in the art that tissue thickness affects the separation distance of the electrodes that is required for effective treatment. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the distance X of Hooven variable depending on the thickness of the tissue between the jaw members.

Response to Arguments

Applicant's arguments filed June 9, 2006 have been fully considered but they are not persuasive.

Regarding independent claim 1, applicant argues that the electrodes of Hooven are disposed on the jaw member and not in the jaw member. Figs. 5, 6, 7, and 9, however, clearly show that electrodes 42, 44, 46, and 48 are flush with the outer surfaces of the jaws 50 and 52 and therefore are disposed in the jaw. Furthermore, Hooven discloses that the jaw members may comprise an elastomeric material such as polycarbonate or ABS as well as Teflon (col. 4, ln. 46-49). Thus, each of the jaw

members of Hooven includes an elastomeric material disposed on an inner facing tissue contacting surface thereof, each of the elastomeric materials including an electrode disposed therein, as claimed.

Applicant further argues that applicant's process of manufacturing the jaw members is clearly different and more complex. The process of manufacturing, however, is irrelevant in an apparatus claim. Even if applicant were to claim the details of such a process in claim 1, it has been held that:

Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) and MPEP 2113.

Applicant further argues that Hooven's use of Teflon does not meet the definition of an elastomeric material. However, as stated previously, Hooven discloses that the jaw members may comprise an elastomeric material such as polycarbonate or ABS as well as Teflon (col. 4, ln. 46-49).

Applicant further argues that Hooven does not disclose a specific compression range at a specific jaw closure force range. However, since applicant discloses in dependent claim 2 that the elastomeric material may include polycarbonate or ABS, polycarbonate and ABS must inherently be adapted to have the specific compression range at the specific jaw closure force range as specified in claim 1. Therefore, the

polycarbonate or ABS jaws of Hooven must inherently be adapted to have the specific compression range at the specific jaw closure force range as claimed.

Applicant further argues that the claimed invention is a tissue or vessel sealing instrument. In response to applicant's arguments, the recitation of "a tissue or vessel sealing instrument" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

Finally, applicant claims that the jaw members are made from a "substantially rigid material". "Substantially", however, is a relative term, and the examiner maintains that the polycarbonate or ABS jaws of Hooven are substantially rigid compared to many softer materials.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not

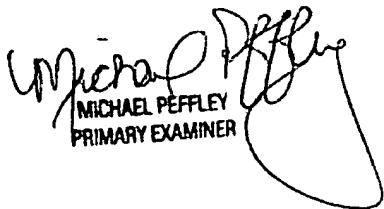
mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alex B. Toy whose telephone number is (571) 272-1953. The examiner can normally be reached on Monday through Friday, 8:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

AT AT
8/9/06


MICHAEL PEFFLEY
PRIMARY EXAMINER